

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

HILTON WASHINGTON, DC/SILVER SPRING
8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND

AUGUST 11, 2009

AGENDA

The committee will discuss a new drug application (NDA) for a radiopharmaceutical proposed for a special type of brain imaging in patients with movement disorders. NDA 22-454, Ioflupane I 123 Injection (proposed trade name DaTSCAN), GE HealthCare, is proposed for detecting loss of functional nigrostriatal dopaminergic neurons by single photon emission computed tomography (SPECT) imaging in patients presenting with symptoms or signs of dopaminergic neurodegeneration.

8:00 a.m. Call to Order and Opening Remarks **Britt Anderson, M.D., Ph.D.**
Acting Chair
Peripheral and Central Nervous System Drugs
Advisory Committee

Introduction of Committee

Conflict of Interest Statement **Diem-Kieu H. Ngo, Pharm.D., BCPS**
Designated Federal Official

8:15 a.m. FDA Introductory Remarks **CAPT Rafel Dwaine Rieves, M.D.**
Director, Division of Medical Imaging and
Hematology Products (DMIHP), Office of Oncology
Drug Products (OODP), OND, CDER, FDA

GUEST SPEAKER PRESENTATIONS

8:30 a.m. Neurodegeneration in Parkinson's
Disease **Ted Dawson, M.D., Ph.D.**
Director, Movement Disorders Center
Johns Hopkins Hospital, Department of Neurology
Leonard and Madlyn Abramson Professor of
Neurodegenerative Diseases
Johns Hopkins University, Institute for Cell Engineering

9:00 a.m. Use of Imaging in Clinical Diagnosis **Joel Perlmutter, M.D.**
Elliot H. Stein Family Chair in Neurology
Professor of Neurology, Radiology, Physical Therapy,
Occupational Therapy, and Neurobiology
Movement Disorders, Department of Neurology
Washington University School of Medicine

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AGENDA
-CONTINUED-

9:30 a.m. **INDUSTRY PRESENTATION**

10: 00 a.m. **BREAK**

10:15 a.m. **INDUSTRY PRESENTATION**

11:15 a.m. Clarifying Questions

11:30 a.m. **FDA PRESENTATION**

12:00 p.m. Clarifying Questions

12:15 p.m. **LUNCH**

1:15 p.m. Open Public Hearing

2:15 p.m. Panel Discussion/Committee Questions

3:00 p.m. **BREAK**

3:15 p.m. Panel Discussion/Committee Questions, Continued

5:00 p.m. **ADJOURNMENT**